OCT 2 6 2001

510(k) SUMMARY K003229

Submitter's Name:	Integra LifeSciences Corporation
Submitter's Address:	105 Morgan Lane Plainsboro, NJ 08536
Submitter's Phone Number:	(609) 936-2311
Submitter's Fax Number:	(609) 897-0645
Name of Contact Person:	Sergio J. Gadaleta, Ph.D. Johnson & Johnson Wound Management, a Division of ETHICON, Inc. Somerville, N.J. (908) 218-2893
Date of Preparation:	October 18, 2001
Name of Device: **Trade Name:** **Common Name:** **Classification Name:**	 BIOPATCH* Antimicrobial Dressing Dressing Unclassified
Legally Marketed Device to Which Equivalency is Being Claimed:	The proposed BIOPATCH* Antimicrobial Dressing is the same (material type, manufacturing methods, sterilization type) as the existing BIOPATCH* Antimicrobial Dressing (K895920).
Description of the Device:	BIOPATCH* Antimicrobial Dressing is an absorptive foam with chlorhexidine gluconate, a well-known antiseptic agent with broad spectrum antimicrobial and antifungal activity.
Intended Use of the Device:	BIOPATCH* Antimicrobial Dressing containing Chlorhexidine gluconate is intended for use as a hydrophilic wound dressing that is used to absorb exudate and to cover a wound caused by the use of vascular and non-vascular percutaneous medical devices such as: • Vascular Devices • IV Catheters • Central Venous Lines • Arterial Catheters • Dialysis Catheters • Peripherally Inserted Coronary Catheters • Mid-Line Catheters • Non-vascular percutaneous devices • Drains • Chest Tubes • Externally Placed Orthopedic Pins • Epidural Catheters It is also intended to reduce local infections, catheter related blood stream infections (CRBSI), and skin colonization of microorganisms commonly related to CRBSI, in patients with central venous or arterial catheters.
Summary of Technological Characteristics Compared to the Predicate Device:	The proposed BIOPATCH* Antimicrobial Dressing is the same (material type, manufacturing methods, sterilization type) as the existing BIOPATCH* Antimicrobial Dressing.

Brief Discussion of Nonclinical Tests:	No new nonclinical tests were required to support the change.
Brief Discussion of Clinical Tests:	A controlled, randomized, clinical trial consisting of 687 subjects with 1699 central venous or arterial catheter insertion sites was conducted at two centers. Results of this study demonstrated: • use of BIOPATCH Antimicrobial Dressing resulted in a statistically significant 44% reduction in the incidence of local infection ($p \leq 0.0001$). • use of BIOPATCH Antimicrobial Dressing resulted in a statistically significant 60% reduction in the incidence of catheter related blood stream infections ($p = 0.026$). • use of BIOPATCH Antimicrobial Dressing resulted in statistically significant reduction in skin colonization of microorganisms commonly associated with CRBSI ($p \leq 0.05$). Patients randomized to the BIOPATCH Antimicrobial Dressing Treatment Group experienced no serious device-related adverse events.
Conclusions Drawn for the Nonclinical and Clinical Tests:	See "Brief Discussion" of Clinical Tests above.
Other Information Deemed Necessary by FDA:	Not Applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2001

Sergio J. Gadaleta, Ph.D.
Senior Project Manager, Regulatory Affairs
Johnson & Johnson Wound Management
A Division of Ethicon
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876-0151

Re: K003229
Trade/Device Name: BIOPATCH Antimicrobial Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 8, 2001
Received: August 10, 2001

Dear Dr. Gadaleta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Wolf, MS

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003229

510(k) Number (if known): K003229

Device Name: BIOPATCH Antimicrobial Dressing

Indications for Use:

BIOPATCH* Antimicrobial Dressing containing Chlorhexidine gluconate is intended for use as a hydrophilic wound dressing that is used to absorb exudate and to cover a wound caused by the use of vascular and non-vascular percutaneous medical devices such as: IV catheters, central venous lines, arterial catheters, dialysis catheters, peripherally inserted coronary catheters, mid-line catheter, drains, chest tubes, externally placed orthopedic pins, and epidural catheters. It is also intended to reduce local infections, catheter related blood stream infections (CRBSI), and skin colonization of microorganisms commonly related to CRBSI, in patients with central venous or arterial catheters.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003229